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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/306,749 05/07/99 MEADE T A-58762-9/RF

HM22/1208

FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP
SUITE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4187

EXAMINER

ZITOMER, S

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/306,749

Applicant(s)
MEADE et al.

Examiner
Stephanie Zitomer

Group Art Unit
1655



☒ Responsive to communication(s) filed on Dec 9, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 12-25 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 12-25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Notice of Allowance vacated: Prosecution reopened

1. Applicant is advised that the Notice of Allowance mailed August 17, 2000 is vacated. Prosecution on the merits of this application is reopened on claims 12-25 considered unpatentable for the reasons indicated below.

Rejection under 35 U.S.C. 101: Lack of specific asserted utility

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 12-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The specification fails to teach the claimed "phosphoramidite nucleoside comprising a covalently attached electron transfer moiety" and thus fails to disclose an asserted specific and substantial utility for the nucleoside. One of skill in the art would not have expected that a nucleoside with attached electron transfer moiety which comprises a transition metal as known in the art and taught in the specification would be readily incorporated during either an enzymatic synthesis or a chemical synthesis due to the bulky structure of such electron transfer groups which would interfere with the necessary contact between the reactants. For example, Bannwarth et al. (5,278,043) discloses nucleic acids in which electron transfer compounds are attached to the terminal nucleotides or are substituted for some of the internal nucleotides. Notably, the reference does not teach the incorporation of nucleosides with bulky electron transfer moieties attached thereto during nucleic acid synthesis. Therefore, the claimed nucleosides do not have an established utility. Furthermore, the specification teaches attachment of the electron transfer moiety to an amino-modified nucleotide after the modified nucleotide has been incorporated into the nucleic acid which teaches away from the claimed "nucleoside comprising a covalently attached electron transfer moiety". Note that because the claimed invention is not supported by a specific asserted utility for the reasons set forth above credibility cannot be assessed.

Rejection under 35 U.S.C. 112, first paragraph: Lack of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12-25 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

4. Claims 12-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although Figures 4A and 4B describe a nucleoside comprising a covalently attached electron transfer group, the specification fails to describe the claimed "nucleoside [or nucleotide] comprising a covalently attached electron transfer moiety". In the method of making nucleic acids comprising electron transfer moieties described in the specification at page 20 and in Example 1 at pages 37-40, the nucleosides are modified by addition of an amino group at the 2' or 3' position and the electron transfer moiety is attached via the amino group after synthesis of the nucleic acid in which the amino-modified nucleosides are incorporated (page 20, lines 10-18).

Furthermore, one of skill in the art would not have expected that a nucleotide with attached electron transfer moiety which comprises a transition metal as known in the art and taught in the specification would be readily incorporated during either an enzymatic synthesis or a chemical synthesis due to the bulky structure of such electron transfer groups which would interfere with the necessary contact between nucleotides. For example, Bannwarth et al. (5,278,043) discloses nucleic acids in which electron transfer compounds are attached to the terminal nucleotides or are substituted for some of the internal nucleotides. Nucleosides with bulky electron transfer moieties attached are not incorporated during nucleic acid synthesis. The present specification simply does not describe a phosphoramidite nucleoside with an electron transfer group attached thereto or a method of incorporating such nucleoside in a nucleic acid during synthesis. In addition to enablement the first paragraph

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of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. It is clear from the lack of description in the specification that applicant did not contemplate the claimed nucleoside comprising a covalently attached electron transfer moiety at the time the claimed invention application was filed.

Provisional double patenting: Obviousness type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 12-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-28 of copending Application No. 09/602,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a nucleoside comprising a covalently attached electron transfer moiety. The claim sets differ essentially in that in the '618 claims the nucleoside is a phosphoramidite nucleoside. However, it would have been obvious to one of ordinary skill in the art to provide the nucleoside in its naturally tri-phosphorylated state for the known benefit of saving time, labor and cost by omitting the phosphoramidite linkage.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

S. Zitomer

Stephanie Zitomer, Ph.D.

October 11, 2000

STEPHANIE ZITOMER
PRIMARY EXAMINER